NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER-LAMBERT COMPANY, Petitioner, v. TEVA PHARMACEUTICALS USA et al. Respondents.	Civil Action No. 99-922 (DRD) **O P I N I O N**

Dickinson R. Debevoise, Senior District Judge

Plaintiff, Warner-Lambert Company ("Warner Lambert"), filed an in limine motion to exclude certain paragraphs of two expert reports of Gilbert S. Banker, Ph.D., D. Sci., who has been retained by defendant, Teva Pharmaceuticals USA ("Teva"). The background of the present motion is set forth in the Court's September 18, 2006 bench opinion (citations omitted):

> The case was started on March 2nd, 1999. On February 28th, 2003, expert discovery closed. On October 2nd, 2003, a summary judgment of infringement of the '450 patent was entered and there was summary judgment that Claims 1, 4 through 10, and 12 were not invalid for obviousness or non-enablement. On June 29th, 2004, after a bench trial, the '450 patent was held to be not unenforceable for inequitable conduct. Claims 16 and 17 were not invalid by reason of anticipation or obviousness. On August 11, 2005, the Federal Circuit reversed the summary judgment of infringement and validity. It remanded the case to address, among other things, issues

of enablement and infringement.

In January, 2006, this Court granted summary judgment of infringement. It denied a summary judgment of enablement. It struck the discoloration defense as untimely.

In December, 2005, expert reports of Dr. Banker and Dr. Coleman were submitted in substitution for the expert reports of Dr. Joseph B. Schwartz of September 20th, 2002, and December 18, 2002.

Teva is entitled to substitute a new expert report for those of its original expert, who was incapacitated, and I understand has now died. The new expert is limited to testimony about opinions disclosed by the former expert Dr. Schwartz. The new expert cannot introduce new and different theories in the case.

First, it would be in order to review the scope of Dr. Schwartz's reports concerning enablement. Teva submitted Dr. Schwartz's principal report, which is dated September 20th, 2002. The bulk of the report concerns asserted invalidity in view of the prior art. Its introductory paragraph summarizes Dr. Schwartz's opinion about enablement.

"It is also my opinion that the asserted claims of the '450 patent are invalid for lack of enablement because the patent did not disclose the role of pH in the '450 patent. Without this disclosure, a person of skill in the art would have to undertake undue experimentation to perform the claimed invention."

It later developed that the theory that the pH controlled the stabilization of ACE inhibitors was rejected both by this court and the Federal Circuit.

Intermingled with his pH theory, Dr. Schwartz advanced another basis to find lack

of enablement, namely, insufficient information was disclosed concerning the amounts of ingredients to enable one to practice the '450 invention.

In his September 20th, 2002, 48-page report, Dr. Schwartz devoted four and a half pages to enablement, and much of that relied on the pH theory. In his December 18th, 2002 report, Dr. Schwartz devoted three pages to enablement, and again much of that material relied on the pH theory.

It is necessary to determine the substance of the enablement opinions that Dr. Schwartz rendered. Referring first to the September 20th, 2002 report, paragraph 118, simply sets forth legal principles concerning Section 112, enablement, and a recital of the eight Wands factors.

Paragraph 119 asserts that without knowing that pH plays a role in the stabilization of quinapril, a person using the '450 patent would have to undertake undue experimentation.

Paragraph 120 to 123 proceed with a discussion of the importance of pH.

Paragraph 124, after its first sentence, moves beyond pH, and notes the wide ranges the '450 patent states for alkali or alkaline earth metal carbonate, the saccharide, and the ACE inhibitor.

Paragraph 125 notes the differences in ratios of carbonate to saccharide in the two examples.

Paragraph 127 states: "However, examples A and B may not be the only potential stable formulations that can be made using the '450 patent. Indeed, if one looks at the dependent claims of the '450 patent, one sees that stable formulations are said to be made with other ACE inhibitors, such as enalapril, and with other saccharides such as manitol.

To stabilize formulations using these ingredients, one would have to experiment.

Paragraphs 128 and 129 set forth other circumstances in which experimentation would be necessary.

Paragraph 130 summarizes Dr. Schwartz's opinion concerning enablement. "Thus, if one of skill in the art were to prepare a formulation using the '450 patent, that was not example A or B, you would have to perform significant experimentation and testing to see whether he could create a stable product."

As to the December 18, 2002 report, paragraphs 34 and 35 concern the asserted significance of pH.

Paragraph 36 sets forth the factors to be considered in determining if experimentation is unreasonable, and, disputing Dr. Amidon's opinions dealing with pH concludes: "I do in fact state in my first report that significant experimentation and testing would be required to determine what formulations would create a stable product based on the '450 patent." He gives his reasons in the next six paragraphs of his report.

Paragraph 37 refers back to paragraph 33, which recites the ten months of experimentation that Teva undertook to develop a stable product.

Paragraphs 38 ad 39 refer back to paragraphs 119 to 130, and 125 to 127 of the September 20th, 2002 report, which opined that the guidance in the patent and in the examples was insufficient.

Paragraphs 40 and 41 again refer to the failure of the patent to provide guidance as to the pH range. Paragraph 40 states: "The nature of the invention is such that incremental changes in the ingredients of the

formulation could have major effects on the stability, manufacturability, and bioavailabity of the product."

Paragraph 42 sums up the non-pH related opinion, which is the one within the confines of which Dr. Banker and Dr. Coleman will have to limit themselves. The 'suitable amount' language in the claims of the '450 patent 5:58.6.2 discloses a range that is so wide that undue experimentation would inevitably be required to give meaning to that language. This is practically the case because the specification makes no meaningful attempt to limit the percentages of excipients that would be useful in the claimed invention. In addition, as Dr. Amidon points out himself in paragraph 48 of his report, a comparison of Warner-Lambert's and Teva U./U.S.A.'s magnesium formulations reveals that the quantity of the excipients used by the two parties was different, pointing to the undue experimentation that the '450 patent required of Teva to achieve a stable formulation successfully."

It is to be noted that Dr. Schwartz offered no evidence of actual inoperative embodiments within Warner-Lambert's claims, none involving fosinopril, enalapril, calcium carbonate, sodium bicarbonate, sodium hydroxide. Nor did he advance inoperative embodiments in documents of other companies such as Merck or Schwartz Pharma. Nor did he advance inoperative embodiments in documents of other companies such as Merck or Schwartz Parma. Nor did he deal with manufacturing variables. He relied on the wide range of ingredients and excipients set forth in the claims, and on the difficulties Teva had when seeking to develop a stable product. It is apparent that the expert opinions of Dr. Banker and Dr. Coleman extend far beyond a fair application of Dr. Schwartz's opinion, and the grounds given for it.

While it is reasonable for a new expert opinion to amplify upon the basic opinion of

> the original expert, it is not reasonable to advance new opinions or provide totally new grounds for the old opinion.
>
> To this extent, the opinions of Teva's new experts will have to be curtailed. Expert discovery in this case was closed on February 28th, 2003. Despite ample opportunity during the extended period of trial, appeal, remand and additional substantive motions, Teva made no effort to implement Dr. Schwartz's report until December, 2005. There is no reason why it could not have moved to supplement the report long ago. The case is approaching trial on the one remaining issue. If the new reports were admitted in their present form, it would be necessary to open a new round of expert discovery. Warner-Lambert would have to re-assemble its own experts and investigate the new material produced. The Court will, therefore address the portions of the proffered reports that Warner-Lambert moves to exclude; namely, Coleman report, paragraphs 2, and 12 through 30; and Banker report, paragraphs 30 to 45, 51 to 87, 90 to 101, 104 to 114, and 116 to 121.

The Court proceeded to conduct the review of Teva's proffered report to determine the extent they advanced new grounds for Dr. Schwartz's opinion. It excluded Dr. Coleman's report in its entirety, stating:

> Dr. Coleman's report in the specified paragraphs is devoted entirely to fosinopril sodium, marketed as an ACE inhibitor under the brand name Maropril by Bristol-Myers Squibb company. After reciting a detailed analysis of the fosinopril consuming seven pages, Dr. Coleman opined that fosinopril undergoes cyclization and/or hydrolysis if fosinopril is subjected to a reaction of magnesium carbonate in water. Dr. Banker relies on Dr. Coleman's analysis in support of his lack of enablement opinion. Dr.

> Coleman's report is so far removed from anything that Dr. Schwartz addressed that it must be excluded in its entirety.

Turning to Dr. Banker's report, the Court struck certain paragraphs, ruling:

> Warner-Lambert moves to strike certain paragraphs of Dr. Banker's report. Presumably it did not object to the other paragraphs. Turning to those which objection is made, first addressing paragraphs 30 to 45, paragraphs 30 to 33 will be stricken. Paragraph 30n refers to tens of thousands of pharmaceuticals incorporating ACE inhibitors or their pharmaceutically acceptable acid addition salts, alkali or alkali earth metal carbonate, or bicarbonates and saccharides.
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> Paragraph 31 addresses dosage forms which was not a subject of Dr. Schwartz's opinion, nor were Schwarz Pharma's assertions referred to in paragraph 32.
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> Paragraph 33 relies on the report of Dr. Coleman, which has been stricken. The first two sentences of paragraph 34 are within the scope of Dr. Schwartz's opinion and can remain. the remainder of the paragraph is beyond his report and will be stricken.
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> Paragraphs 35 and 36 are within the fair scope of Dr. Schwartz's report and can remain.
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> Paragraph 37 is outside the scope of Dr. Schwartz's report and will be stricken.
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> There is only the most casual reference to manufacturing processes in the Dr. Schwartz report, and it does not develop a relationship to enablement. Consequently, paragraph 38 will be stricken.
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> Paragraph 39 reflects Dr. Schwartz's report and can remain.

Paragraph 40 can remain upon deletion of "the number of dosage forms" and "the range of manufacturing techniques."

Paragraph 41 to 45, except for the last two sentences of paragraph 45 are within the scope of Dr. Schwartz's opinion and can remain. The last two sentences in paragraph 45, which hypothesize direct compression, or dry granulation, and wet granulation stray too far from Dr. Schwartz's opinion and will be stricken.

Paragraphs 51 to 87. Paragraph 51 through 58 will be stricken. They deal with subjects that there were not the basis of Dr. Schwartz's opinion. The first 3 sentences of paragraph 59 can remain as within the scope of Dr. Schwartz's opinion. The balance of paragraph 59 and paragraph 60 through 65 will be stricken, as they deal with direct compression, dry granulation, and wet granulation, which were not a basis of Dr. Schwartz's opinion.

Paragraph 66 to 78 deal with Merck's experiences in stabilizing enalapril with sodium bicarbonate. They will be stricken as those experiences were not a basis for Dr. Schwartz's opinion. Nor were Warner-Lambert's experiments when developing quinapril a basis for Dr. Schwartz's opinion, and consequently paragraph 79 to 87 will be stricken.

Paragraphs 90 to 101. Paragraphs 90 to 97 rely upon Schwartz Pharma's attempts to stabilize moexipril with magnesium carbonate. This was a not a basis for Dr. Schwartz's opinion and those paragraphs will be stricken. Paragraphs 98 to 101 describe the results of Dr. Coleman's studies of fosinopril. They were not relied upon by Dr. Schwartz, and those paragraphs will be stricken.

Turning to paragraphs 104 to 114. Paragraphs 104 to 114 seek to apply the

> opinions contained in the preceding paragraphs to dependent claims 4 through 10, 12, and 17. Thus, by reference, they incorporate material that has been stricken. They will be stricken in their present form, but may be rewritten so as to incorporate only material that has not been stricken.
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> Paragraph 116 to 121. Paragraphs 116 to 119 will be stricken, as they contain material already stricken from earlier paragraphs. Paragraphs 120 and 121 will be permitted to stand, except that the words "and what kind of dosage form (tablet? capsule?) to develop" appearing in the eleventh line of paragraph 120 will be stricken for consistency with rulings concerning other paragraphs.

An order was entered incorporating this opinion. In summation, it required that Teva's enablement experts not offer opinions concerning: i) alleged inoperative embodiments within Warner-Lambert's claims, ii) alleged inoperative embodiments described in Warner-Lambert, Merck or Schwarz Pharma documents, iii) manufacturing variables, iv) fosinopril sodium, v) alternative dosage forms; vi) direct compression and dry granulation, vii) difficulties optimizing a pharmaceutical product with multiple degradation pathways, and viii) Merck's and Warner-Lambert's and Schwarz Pharma's efforts to develop a stabilized ACE inhibitor composition. In other words, Teva's experts were not to proceed beyond Dr. Schwartz's two enabling arguments, namely: i) the '450 patent fails to address the role that pH plays in the stability of ACE inhibitor and ii) in view of the many variables involved, the '450 patent disclosed too

little information regarding the amounts of ingredients and manufacturing details to enable one skilled in the art to produce the '450 invention.

Teva submitted a new expert report of Dr. Banker on November 7, 2006. Warner-Lambert submitted a twenty-four page, January 4, 2007 answering report of Dr. Amidon (the "Amidon Report"), and on February 9, 2007 Teva submitted a purported reply to Dr. Amidon's report. Warner-Lambert contends that Teva's November 7, 2006 and February 9, 2007 reports attempt to re-introduce expert opinions previously excluded by the court and introduce an entirely new expert opinion. Warner-Lambert moves to exclude the expert opinions found in paragraphs 24, 31, 35, 43 and 49 of the November 7, 2006 report and paragraphs 3-6, 8-12, 18-23, 25-29, 33, 45 and 46 of the February 9, 2007 report.

II. Discussion

Teva argues, in effect, that even though a considerable portion of Dr. Banker's reports goes beyond that which is allowed by the court's September 18, 2006 opinion, it is permissible as a response to new matter contained in the Amidon Report. It comes within Fed. R. Civ. P. 26(a)(2)(C), which contemplates the later disclosure of expert opinions that are "intended solely to contradict or rebut evidence on the same subject matter identified by another party." TC Systems Inc. v. Town of Colonia, 213 F. Supp. 2d 171, 177-80 (N.D.N.Y. 2002).

As a starter, Teva points to the last paragraph (48) of the Amidon Report which states ". . . I conclude that the asserted claims of the '450 patent are not invalid for lack of enablement." Teva argues that because Dr. Amidon did not previously opine that the '450 patent is enabled, "the Banker Reply in its entirety is directly responsive to Dr. Amidon's affirmative opinion that the claims-in-suit are enabled." In his October 25, 2002 and his March 12, 2004 opinions Dr. Amidon, in opposing Dr. Schwartz's opinions, expressed the opinion that the '450 patent is enabled. Reiterating that opinion on January 4, 2007 did not constitute new matters, opening the door to Dr. Banker to give ful range to his prior new opinions that had previously been barred.

Turning to the subjects of Dr. Banker's two reports that Warner-Lambert seeks to strike:

Para 24 of November 7, 2006 Report: Up to the last sentence of Para 24, it, like the immediately preceding paragraphs, simply recites what the patent states. That is unobjectionable. The last sentence, however, feeds into the excluded opinion that the patent is not enabled because of the multiple dosage forms. That sentence will be stricken.

Para 31 of November 7, 2006 Report: In this paragraph's last two sentences Dr. Banker contends that the '450 patent is not enabled because "[c]hemical differences among the acid addition

salts of drug compound may affect the stability of the resulting dosage forms." This is also an excluded opinion. It is not, as Teva contends "simply another dimension of the 'breadth of the claims' that Dr. Schwartz identified," nor is it, as Teva argues, "directly responsive to Dr. Amidon's opinion that the full range of claims is enabled." Accordingly the last two sentences of Para 31 will be stricken.

Para 35 of the November 7, 2007 Report: The first Para 35 appearing in this report also relies on the dosage argument. It contains the language "could be combined to formulate a dosage form." As consistent with the September 18, 2006 ruling of the court, there shall be stricken from para 35 the words "that could be combined to formulate a dosage form."

Para 43 of the November 7, 2007 Report: Para 43 is devoted almost entirely to the manufacturing argument, a subject decisively excluded in the September 18, 2006 opinion. Nothing in the Amidon Report justifies reintroducing it, and the entire paragraph will be stricken.

Para 49 of the November 7, 2007 Report: In this paragraph Dr. Banker introduces a new basis for finding lack of enablement. Specifically, he notes that the inventors discovered that adding buffers to modify the pH of the dosage form was by itself insufficient to stabilize ACE inhibitors. He then opines that "without any further explanation of the role of pH in the

stabilization process has the perverse effect of providing 'negative' guidance, i.e., steering persons of skill in the art reading the patent to pursue avenues that, in the end, are unlikely to prove successful, i.e., attempting to identify the 'stabilizing' pH and adding sufficient buffer to achieve it." This is an altogether new ground not advanced by Dr. Schwart and will be excluded.

Feb. 9, 2007 Report concerning dosage forms: The September 18, 2006 ruling that Dr. Banker's opinion relying on alternative dosage forms should be excluded, is violated in a number of places in his February 9, 2007 report as well as in Paras. 24 and 35 of his November 6, 2007 Report. The offending sections are Paras. 3 (last sentence); 5 (fifth sentence); Paras. 8-12, 27, 29, 45 and 46. They will be stricken.

Feb. 9, 2007 Report concerning inoperative embodiments: In a number of places in Dr. Banker's Feb. 9, 2007 report he relies upon the inoperative embodiments within the '450 patent claims, in documents of other companies such as Merck and Schwarz Pharma, and in Merck's, Warner-Lambert's and Schwarz Pharma's experiments when developing a stabilized compound. These were not the subject of Dr. Schwarz's opinion. They were excluded in the September 18, 2006 opinion. They must be excluded where they appear in the February 9, 2007 Banker report, namely, at: Para 4 (which is not a justifiable rebuttal of Dr. Amidon's Report);

Para. 21, first sentence; Para. 25; Para. 27; Para. 28; the sentence in Para. 38 reading "As the Court noted (Slip. Op. at 8), Merck discovered that raising the pH of its enalapril formulation reduced cyclization but increased hydrolysis."

Feb. 9, 2007 Report concerning manufacturing variables: Warner-Lambert seeks to strike the fourth sentence of Para. 5 and the third sentence of Para. 6. These sentences do not appear to come within the scope of the forbidden materials and will not be stricken. Paras. 22, 23 26 and 27(b) come within the prohibitions recited above and will be stricken.

Feb. 9, 2007 Report concerning direct compression and dry granulation: On September 18, 2006 the court held that direct compression and dry granulation were not the subject of Dr. Schwarz's reports and this could not be the basis of Dr. Banker's report. Para. 43 of the Nov. 7, 2006 has already been stricken on other grounds, but it should also be stricken for intruding into the subject of direct compression and dry granulation. Paras. 18-21 of the February 9, 2007 Report suffer from the same defect and must be stricken.

Teva does not contend that the struck portions of Dr. Banker's opinions are not within the prohibitions of the court's September 18, 2006 ruling. Rather, it is Teva's contention that the ruling is superseded by Rule 26(a)(2)(C), and that Dr. Amidon's answering report has opened the door to the opinions of

Dr. Banker that the court previously excluded. His answering report, however, does not go beyond the basic position that he has made all along-that it would not take undue experimentation to practice the '450 patent and giving reasons for that position. For example, Teva points to Para. 24 through 29 of Dr. Amidon's answering report in which he contends that a formulator would be able to make and use new drug formulations covered by the '450 patent, beyond just quinapril formulations, using routine experimentation following the working examples and guidance provided in the specification. He then proceeds to describe how in 1986 a formulator would routinely go about doing this. He is not taking the position that a formulator would succeed with any combination he tried and his observations in this regard are not a basis for expanding the areas that Dr. Banker can address.

Teva critiques Dr. Amidon for dealing only with wet granulation, for which the '450 patent expresses a preference. This does not expand his earlier opinion and is not a basis for Dr. Banker to put forth opinions, previously excluded, concerning assertedly inoperative embodiments of dry granulations.

Similarly, the other elements of Dr. Amidon's answering report do not introduce new elements that justify vacating or departing from the court's September 18, 2006 opinion and order. Consequently, Warner-Lambert's motion will be granted to the

extent set forth in this opinion. An order to that effect will be filed[1].

/S/ Dickinson R. Debevoise
DICKINSON R. DEBEVOISE
U.S.S.D.J.

April 20, 2007

[1] In a footnote to its Brief Warner-Lambert objected to Teva's Fourth Supplemental Response to Plaintiffs' Interrogatory No. 4 that disclosed the same new enablement defenses the court excluded on September 18, 2006. This was not a formal part of Warner-Lambert's motion, and the court will not address the objection at this time.